

Remarks

The Abstract and paragraphs [0003], [0036], [0040], [0044], [0048] and [0052] in the description have been amended for editorial purposes.

Claims 1 to 15 are presently pending. Claims 1, 4 and 9 have been amended, without prejudice. In view of the foregoing amendments and the following remarks, reconsideration and withdrawal of the rejections are respectfully requested.

Summary of the Invention

The use of AMP579, an adenosine A1/A2 agonist, to provide cardioprotection in a patient experiencing reperfusion is known in the art. Prior art methods of administering such compounds teach that AMP-579, for example, should be administered up to 90 minutes prior to reperfusion and continuing for a period of 60 minutes following reperfusion to obtain a cardioprotective effect. Those of ordinary skill in the art, however, are cognizant of the negative side effects of such prior art processes such as, for example, hypotension. Contrary to the teachings in the art, applicants have discovered that the cardioprotective benefit of adenosine A1/A2 agonists can be maximized while minimizing hypotension by administering such compounds for a shorter duration, namely by beginning at a time less than 10 minutes after the onset of reperfusion, at reperfusion, or ten minutes before reperfusion, and continuing for a period of more than 30 minutes following the onset of reperfusion.

Discussion of the Rejection under 35 U.S.C. § 102(b)

Claims 1 to 6, 8 to 13 and 15 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Clark et al., Cardiovascular Drug Reviews, 18(3):183-

210 (2000) (hereinafter “Clark”). Applicants respectfully traverse this rejection because Clark does not disclose each and every element of applicants’ claimed invention.

Claim 1 and Claims 2 to 8 which are dependent therefrom require the administration of an adenosine A1/A2 agonist beginning at a time *less than 10 minutes after* the onset of reperfusion *and continuing for a period of more than 30 minutes following* the onset of reperfusion. Claim 9 and Claims 10 to 15 which are dependent therefrom require such administration at a time *10 minutes before* the onset of reperfusion *and continuing for a period of more than 30 minutes after* the onset of reperfusion.

In contrast, Clark does not disclose the claimed treatment combination of (1) initial treatment less than 10 minutes after or 10 minutes before the onset of reperfusion and (2) continuous treatment thereafter for a period of more than 30 minutes after the onset of reperfusion. Clark discloses, for example, that the AMP579 treatment provides cardioprotection when administered at a time *50 to 90 minutes prior to* the onset of reperfusion and *continuing for a period of 60 minutes following* the onset of reperfusion. (See Clark, p. 188, paragraph 2 and Figure 2). Thus, Clark teaches that a *far longer duration* of AMP579 treatment is required in order to obtain a beneficial cardioprotective effect. Indeed, applicants have discovered that, contrary to such prior art teachings, a less extensive duration of treatment maximizes the beneficial cardioprotective effect while minimizing the hypotensive side effect.

Clark discloses also that AMP579 treatment provides cardioprotection when administered 10 minutes prior to the onset of reperfusion. (See Clark, p. 191, paragraph 2). This single administration, however, does not teach or suggest the *continuous* treatment recited by the present claims. Thus, for at least these reasons, Clark does not anticipate applicants' claimed invention.

Indeed, not only is Clark insufficient to anticipate applicants' claimed invention, but Clark is also insufficient to render such claims obvious. Clark does not disclose any modification of the initial treatment timing or the duration of continuous treatment for the purpose of maximizing the cardioprotective benefit or minimizing undesirable side effects of such treatment, such as hypotension. Therefore, Clark does not provide any motivation or suggestion to one of ordinary skill in the art to select the claimed treatment range. Thus, applicants submit respectfully that Clark does not render the claimed invention obvious. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) are requested respectfully.

Discussion of the Rejections under 35 U.S.C. § 103(a)

Claims 7 and 14 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Clark as applied to Claims 1 to 6, 8 to 13 and 15, and further in view of Berge et al., Journal of Pharmaceutical Sciences, 66(1):1-19 (1977) (hereinafter "Berge"). Applicants respectfully traverse this rejection as Clark does not teach or suggest the claimed invention. As detailed above, Clark does not disclose applicants' invention as defined by the independent claims.

The Action cites Berge for the general disclosure of methods for the conversion of compounds into salt forms. Accordingly, even if Berge did disclose the additional recitations of Claims 7 and 14 (arguendo), the combination of Clark and Berge would still not teach or suggest each and every element of the base claims. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are requested respectfully.

Conclusion

Applicants submit respectfully that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is authorized hereby to charge any fees or credit any overpayment associated with this Reply (copy enclosed) to Deposit Account Number 19-5425.

Respectfully submitted,



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